SUMMARY OF THE ENVIRONMENTAL LABORATORY ADVISORY BOARD MEETING JUNE 6, 2003

The Environmental Laboratory Advisory Board (ELAB) met on June 6, 2003, at 8:30 a.m. Chairperson Ms. Zonetta English of the Louisville/Jefferson County MSD led the meeting. A list of action items is given in Attachment A. A list of participants is given in Attachment B. The meeting agenda is given in Attachment C.

INTRODUCTION

Audience members at this public meeting were provided with a packet of handouts including the meeting agenda, a copy of ELAB's charter, a summary of the legal requirements of the Federal Advisory Committee Act (FACA), a draft copy of the minutes of ELAB's May 28, 2003, teleconference, and a listing and status update of ELAB's recommendations (dated August 22, 2000).

Mr. John Bigmeat and Dr. Michael Green joined the meeting via teleconference line. After verifying that the connection with Mr. Bigmeat and Dr. Green had been made, ELAB's Designated Federal Officer (DFO), Ms. Lara Autry of the U.S. Environmental Protection Agency (EPA), opened the meeting. Ms. Autry briefly reviewed the meeting's ground rules. She noted that items discussed in the Open Forum held earlier in the week would constitute an addition to the preprinted agenda. She then turned the meeting over to Ms. English. Following introductions of ELAB members, Ms. English asked members of the audience to limit their comments to three minutes in length. She noted that ELAB would try to move through the agenda as efficiently as possible to accommodate the travel plans of all in attendance. She urged audience members to submit written comments to any member of ELAB via email.

Ms. English then asked Mr. Jerry Parr to step forward. On behalf of the members of ELAB, she presented Mr. Parr with a plaque in recognition of his many years of service to ELAB and the NELAC community. She noted that ELAB would also be recognizing Dr. Harry Gearhart, who was retiring from Dupont and had been unable to attend the meeting. Ms. English expressed her sincere thanks to Mr. Parr and Dr. Gearhart.

Ms. English led a review of minutes from ELAB's May 28 teleconference meeting. The minutes were approved pending the correction of a typographical error.

REVIEW OF ACTION ITEMS

Following approval of minutes, Ms. English moved to a review and status update of action items, as follows:

• Nonparticipating Laboratories: In discussion of this action item, Dr. Mark Marcus suggested that the present draft language on the nonparticipation issue be included on the agenda for ELAB's next teleconference for discussion to decide whether future action is necessary. Ms. English noted that she had confirmed that Ms. Silky Labie, Chair of the NELAC Small Organizations Committee, had received a copy of the nonparticipation

problem statement prepared by Mr. Parr during his service on ELAB. She invited Ms. Labie to summarize the discussion in her committee's open session held earlier in the week. Ms. Labie reported that many small organization concerns actually apply to any organization. She reported that participants in the Small Organizations session had indicated that there is a need for simplicity to be able to understand how the accreditation process works for each individual organization. It was suggested that a flow chart or "road map" would be helpful. Ms. Labie reported that Mr. Charles Dyer of the State of New Hampshire is spearheading a distillation of the NELAC Standards for elements that do apply to small organizations. She also noted that there had been discussion of outreach and marketing with an awareness of budgetary issues. Small organizations often do not have the necessary funds to send people to meetings. Therefore, alternate methods of information delivery (email, web-based training, information disseminated through professional organizations, etc.) are attractive. Ms. Labie noted that the Small Organizations Committee will identify appropriate groups to disseminate information within each state after the committee is reconstituted under the Institute for National Environmental Laboratory Accreditation (INELA) She also noted that basic questions about the impact of the NELAC Standards had been raised in discussion. (Are the standards cost-effective? Have they improved data quality?)

Ms. English opened the issue to the floor for further discussion. There was substantial discussion of small organization issues versus nonparticipation issues. It was suggested that ELAB's effort should be to address nonparticipation in the NELAC process, including states and EPA program offices in addition to laboratory and field measurement and sampling organizations (FMSOs). There was discussion of whether the Small Organizations Committee scope was limited to laboratories and FMSOs. A representative from an approved National Environmental Laboratory Accreditation Program (NELAP) Accrediting Authority indicated that some states will not be able to join NELAP until the small organization issue is resolved. Another state representative suggested that the biggest difference between the small organization and nonparticipation issues is that larger laboratories and states ask, "What are we getting for our money?" while small organizations ask, "Do we have the resources to make this happen?" It was suggested that ELAB focus on two issues: benefit to the laboratory to be accredited and whether NELAC is a good accreditation system. Ms. Labie noted that her committee would be calling upon the marketing expertise in the stakeholder community. She also noted that it is the intent of the committee to identify elements of the NELAC Standards that are not applicable to a laboratory because of its function rather than its size.

It was noted that this effort is linked to ELAB's review and support of the September 2002 letter from the Environmental Council of States (ECOS) to EPA in support of NELAC. Mr. Robert Wyeth indicated that he had taken the lead on behalf of ELAB on the effort to draft language in support of the ECOS letter. In conclusion, Ms. English summarized the issue on behalf of ELAB. She noted that ELAB's focus is the nonparticipation issue, of which the small organization issue is a part. ELAB will advise EPA on the nonparticipation issue and keep Ms. Labie informed of their progress. The activities of ELAB and the Small Organizations Committee will occur concurrently.

There was additional discussion of the standards adopted by NELAC and questions of the ease with which they could be changed. Mr. Parr noted that INELA will copyright its standards. Although INELA will provide its standards to any organization, organizations will not be free to change the standards.

- White Paper on Restructured NELAC: Dr. Marcus explained that he had written a white paper addressing the requirements of the National Technology Transfer and Advancement Act (NTTA), which establishes the policy from Office of Management and Budget (OMB) Circular A-119 into law. Noting that he was soliciting input on the paper from ELAB, Dr. Marcus proposed that ELAB include discussion of the white paper on the agenda for its next teleconference.
- ELAB Letter in Support of ECOS Letter Mr. Robert Wyeth explained that ELAB had received a copy of a September 2002 letter from the Environmental Council of the States (ECOS) to EPA encouraging EPA to continue its support of and participation in NELAC. He further explained that ELAB is drafting its own letter recommending EPA's continued support of NELAC, using the ECOS letter as an example. Mr. Wyeth recommended that ELAB include the letter on the agenda for its next scheduled teleconference.
- Homeland Security Issues Dr. Michael Green led discussion of homeland security issues. He explained that ELAB had discussed two principal issues in regard to the question of whether NELAC should develop a framework to address security issues the chemical industry has found to be of importance. The first issue relates to the question of whether laboratories have reviewed and identified their critical analyses, such as those associated with public drinking water supplies. Dr. Green reviewed possible options for addressing this issue, such as adopting a system linked to the Office of Homeland Security alert levels to develop enhanced data review levels, opening dialogs with clients to establish protocols for performing analyses on a more frequent basis, or information-sharing through analysis centers supplied with information from a material infrastructure protection center. Dr. Green noted that the second issue discussed by ELAB relates to inventory control in laboratories of agents on the weapons of mass destruction list, such as ammonia, hydrochloric acid, nitric acid, and sulfuric acid. He noted that there have been past incidents in which individuals have stolen or purchased these chemicals over a period of time and that greater inventory control results in greater security.

In subsequent discussion from the floor, a representative of a NELAP-accredited laboratory noted that his laboratory had been involved in two terrorism alerts associated with public drinking water supplies. He noted that law enforcement officials were not familiar with laboratory methods and quality assurance (QA) requirements, and that speed was of great importance in homeland security analyses. He suggested that the laboratory community needs generalized scan methods that cover broad views, different data quality objectives, and guidelines for homeland security analyses. In response, an employee of EPA suggested that there is already a great deal of activity at the federal level to address the homeland security issue. He noted that it would be helpful if laboratory experts volunteered to help the federal government in their work to address homeland security, but suggested that it would not be the most efficient use of ELAB's

time. In conclusion, the members of ELAB agreed that they would include the issue on the agenda for ELAB's next scheduled teleconference.

REVIEW OF PAST ELAB RECOMMENDATIONS

Ms. English directed attendees' attention to the August 2000 table of ELAB recommendations that had been provided as a handout. In brief discussion of the recommendations, it was noted that the status of Recommendation Number 29 ("ELAB recommends that EPA and the Department of Transportation address the inconsistencies between the EPA preservation requirements and the DOT shipping requirements." 7/1/98) had changed to "Completed" when DOT published a memorandum on the issue. It was noted that the memorandum is available on the EPA Office of Solid Waste website. Ms. English noted that the table is outdated and that ELAB will work to revise and update it. Noting that a review by NELAC stakeholders would be helpful, she urged attendees to submit comments on old recommendations to her in writing via email.

OPEN FORUM ISSUES

Ms. English enumerated issues that were raised in the ELAB Open Forum on June 3, 2003. Their disposition is summarized as follows:

- 1. Recommendation that ELAB ask EPA representative to write letter of appreciation to retiring ELAB members Ms. Autry noted that she would address this issue.
- 2. EPA Office of Water Federal Register notice on issue of method detection limits (MDLs) request ELAB take up as an issue in consideration of technical soundness of MDL proposal, quantitation issues, long-term variability as key monitoring to assure laboratories can generate MDLs on an ongoing basis, method blank/blank concentration issues, issues of economics and customer/client demands on MDL, and need for definition and documentation of intended use and usability of MDL

There was some discussion of whether ELAB can submit comments to the federal rulemaking process. It was noted that ELAB can submit comments, but they must be submitted through the DFO. In subsequent discussion, it was noted that the proposed rule has an impact greater than the Office of Water; it impacts NELAC and other matrices. Speaking on behalf of the American Council of Independent Laboratories (ACIL), Mr. Wyeth noted that ACIL intends to present its comments to EPA in response to the Office of Water's MDL announcement. Since several individuals asked ELAB at the Open Forum to also address the issue, Mr. Wyeth offered to draft a letter on behalf of ELAB. He noted that the letter would not be in support of ACIL's specific approach, but would identify the MDL issue as a critical issue that must be addressed. Mr. Wyeth indicated that he would complete the draft by June 13, 2003. It was suggested that the letter indicate that ELAB would like EPA to address the issue at the highest possible agency level since it impacts all EPA program offices. An EPA employee suggested that ELAB consider a broader focus, i.e. what lower limit of measurement can laboratories realistically reach with the expected confidence level. He suggested that this issue goes to the heart of the intended use of data and recommended that ELAB ask the agency to look at the problem holistically rather than narrowing its focus on MDL. After

subsequent discussion, the members of ELAB agreed to couple the issue with Issue 7 (suggestion that ELAB advise EPA on how to develop scientifically defensible sensitivity) below.

3. Suggestion that ELAB consider interaction with Forum on Environmental Measurements

In discussion from the floor, it was explained that the Forum on Environmental Measurements is a senior management group recently formed by EPA to address measurement science issues and cross-program issues. The forum reports to the agency's Science Policy Council and addresses minimum requirements for validation and peer review of the agency's methods before their release, development of a system for quickly identifying and rectifying situations in which a method proves unsuitable for a given purpose, improvement of the agency's internal quality system at its laboratories, and acceleration of the agency's adoption of performance-based measurements in its program offices. Mr. David Friedman of the EPA indicated that he would be developing a website for the Forum on Environmental Measurements within the next four to six weeks. Mr. Parr indicated that he had obtained a copy of the forum's charter and would soon be making it publicly available at http://www.catalystinforesources.com. Mr. Parr offered to email a copy of the charter to Ms. English.

After some discussion, Ms. Elaine LeMoine and Dr. Marcus indicated that they would coordinate to lead ELAB's effort to interact with the Forum on Environmental Measurements. Noting that ACIL is also attempting to take an active part in the forum, Mr. Wyeth indicated that he would share information with the workgroup formed by Ms. LeMoine and Dr. Marcus.

4. NELAC membership issue - suggestion that participation in NELAC would increase if EPA held state laboratories to NELAC standards

Ms. Autry read a letter from Mr. James Bentley, who had made the original comment at the ELAB Open Forum but had been unable to attend this meeting. Mr. Bentley's letter suggested that it may be possible for EPA to require state laboratories to meet NELAC/NELAP standards. The letter further suggested that such a top-down effort combined with a grassroots-level effort could result in increased participation in NELAC, but acknowledged the potential states rights issue associated with mandating adherence.

In discussion from the floor, an EPA employee suggested that Mr. Bentley's letter raised two separate issues: 1) the request for EPA to become an accrediting authority, and 2) mandating state laboratories to be accredited. He noted that the latter is a problematic issue because EPA is prescribed from unfunded mandates. After subsequent discussion, the members of ELAB noted that the issue warrants additional ELAB discussion and agreed to couple the issue with Issue 6 (impact of NELAC/NELAP on laboratory data quality) below.

5. Suggestion that ELAB revisit the stack emissions issue after expiration of a two-year moratorium

It was suggested that the INELA Field Activities Committee and other standards committees should revisit the stack emissions issue and that the issue is not an ELAB issue. In discussion from the floor, it was suggested that NELAC should identify and adopt stack emissions standards developed by other organizations. Ms. Autry noted that this is a NELAC Standards Review Committee issue and that a field testing standard is close to completion. There was significant discussion of ELAB's role and the most effective way for ELAB to interact with EPA's Office of Air after having issued the moratorium two years ago. In conclusion, ELAB agreed to write a letter to EPA to recommend that EPA request that the NELAC Board of Directors (BoD) work with the Office of Air to reestablish their participation in the stack emissions process. Ms. English noted that she would draft the letter for ELAB review and comment.

6. Has NELAC/NELAP improved data quality? - suggestion that ELAB consider quantitative study to document impact of NELAC/NELAP

There was considerable discussion from the floor on the issue of NELAC's impact on laboratory data quality. Comments were, for the most part, supportive of NELAC. Audience members were in general agreement that they would welcome a quantitative study conducted by an independent organization to document NELAC's impact on the environmental community. Ms. Ilona Taunton noted that the survey of accrediting authorities conducted by Test America on behalf of the NELAC Regulatory Coordination Committee found that the NELAC standards have resulted in a more defensible product. She also noted that the proposed INELA Coordination Committee may move forward with the survey. Noting that the data produced by laboratories today is of higher quality than that produced five to ten years ago, an audience member suggested that any quantitative study should look at the data validation arena and the amount of data that is rejected. Dr. Marcus noted that quality is often in the eyes of the customer and suggested bench marking customers pre- and post-NELAC. Ms. Labie echoed Dr. Marcus' observation, noting that comments in the Small Organizations Open Forum were specifically directed to data usability and suggesting that the critical question is, "Is the data useable as it is provided to the customer?" A representative from an approved NELAP Accrediting Authority urged ELAB to include accrediting authorities in any quantitative study. In conclusion, ELAB agreed to couple this issue with Issue 4 (suggestion that participation in NELAC would increase if EPA held state laboratories to NELAC standards) above.

7. Suggestion that ELAB advise EPA on how to develop scientifically defensible sensitivity (reference to limits of detection (LODs), limits of quantitation (LOQs), method detection limits (MDLs), etc.)

It was decided that this issue is related to Issue 2 (Office of Water Federal Register notice on MDLs) above. ELAB agreed to couple the two issues as they address them in future discussions.

8. Resolution of differences in NELAP assessor interpretations - to whom do laboratories appeal? - It was noted that this issue had been resolved. Chapter 6, Appendix A, of the NELAC Standards provides a process for resolution of interpretational issues.

NEW BUSINESS

After ELAB's Open Forum issues were addressed, Ms. English opened the floor to discussion of new business. The following issues were raised:

- National Database: A representative of a commercial laboratory stated that the national database is in a state of chaos and urged ELAB to write a letter to EPA asking them to cease their efforts on the national database. He suggested that the amount of money that has already been invested by EPA in the effort is a cause of concern for taxpayers. Suggesting that the federal structure is not best suited to the effort and that there are more cost-effective ways to approach the national database, he asked ELAB to write a letter with a two-fold purpose: 1) to express concern about funding, and 2) to present alternatives. In response, an EPA employee who had been present in the NELAC National Database Committee session noted that there had been discussion suggesting that the committee ask the NELAC BoD to write such a letter. Noting that his understanding was that the committee decided to let database efforts proceed in parallel, he suggested that ELAB contact the National Database Committee chair to get clarification. Noting that the agency had already committed an additional \$80,000 to the project and that a work product was expected in approximately one month, Ms. Autry suggested that the effectiveness of the letter would be dampened. It was noted that an estimated \$10,000 to \$30,000 would be needed to bring the database to the present fields of testing need. Suggestions for course of action for ELAB included adopting a waitand-see approach and writing a letter to EPA recommending that no further work on the project be performed after the \$80,000 dollar investment was exhausted. It was decided that Ms. English would request additional information from the appropriate parties to enable ELAB to make a valid assessment of the issue
- Uniformity among analyte lists for different accrediting authorities: A member of ELAB suggested that many laboratories are forced into having multiple accreditations because of differences in lists of analytes included in the accreditation process for different accrediting authorities. The issue of bringing a degree of uniformity or understanding and agreement between the different analyte lists was noted as an issue of concern. Discussion from the floor indicated that the issue impedes the implementation of a national accreditation program. One commenter suggested that the number of fields of accreditation is an issue and that the program needs to collapse to a broader fields of accreditation list to be successful. After moderate discussion, it was decided that ELAB would recommend that EPA advise NELAC to develop the degree of mutual reciprocity necessary to reduce the number of primary accreditations required and to develop a broader agree of acceptance between analyte lists.
- **ELAB meeting schedule:** Ms. Autry requested that ELAB develop its teleconference schedule. In response, Ms. English noted that she had gotten input from the members of

ELAB and would forward that information to Ms. Autry. It was noted that ELAB's next face-to-face meeting date has not been decided. In response, Mr. Parr noted that INELA would welcome ELAB's presence at its January 2004 conference in Dallas, Texas, and that he would make a meeting room available to ELAB. An audience member suggested that ELAB recommend the coordination of INELA and NELAC conferences to minimize the number of conferences each year. In response, Ms. Autry stated that NELAC would make every administrative effort to schedule its meetings to coordinate in the most reasonable fashion with the schedules of all standards development organizations under consideration. She noted, however, that NELAC cannot favor any particular relationship with any one standards development organization.

CONCLUSION

In conclusion, Ms. English thanked the members of ELAB and the audience for their participation. She then turned the meeting over to Ms. Autry. Ms. Autry made several closing remarks. She noted that the current ELAB charter would expire in July 2003 and that a new charter was under reconstitution to take effect two days before the expiration of the current charter. She also noted that ELAB is actively seeking new membership to grow to approximately fifteen members as stated in its charter. Ms. Autry noted that nomination forms are available and that completed nomination forms should be submitted to her for consideration. She also noted that she would be issuing a Federal register notice seeking new members and that the notice would point interested parties to the nomination forms. With no further business to discuss, Ms. Autry adjourned the meeting at approximately 10:30 a.m.

ACTION ITEMS ENVIRONMENTAL LABORATORY ADVISORY BOARD JUNE 6, 2003

Item No.	Action	Date to be Completed or Status Report Given
1	ELAB will include review of language drafted by Mr. Wyeth in support of the September 2002 ECOS letter on the agenda for next teleconference. (Will address NELAC nonparticipation issue, of which the small organizations issue is a part, and will keep Small Organizations Committee chair informed of progress.)	
2	ELAB will include discussion of Dr. Marcus' white paper on the use of voluntary consensus standards on the agenda for next teleconference.	
3	ELAB will include homeland security issues on the agenda for next teleconference.	
4	ELAB will review past recommendations table to update/revise, in consideration of any comments received from stakeholders after NELAC 9.	
5	Ms. Autry will request letters of appreciation for retiring/outgoing ELAB members from appropriate EPA personnel. (6/6/03 Open Forum Issue 1)	
6	Mr. Wyeth will draft a letter identifying the MDL, LOD, LOQ sensitivity issue as a critical issue that must be addressed, for ELAB review and comment. (6/6/03 Open Forum Issues 2 & 7)	
7	Ms. LeMoine and Dr. Marcus will form workgroup to lead ELAB's effort to interact with the Forum on Environmental Measurements. (Mr. Wyeth will share information with the workgroup on behalf of ACIL.) (6/6/03 Open Forum Issue 3)	
8	ELAB will address NELAC participation issues as related to advisability of EPA requiring state laboratories to meet NELAC standards and lingering questions of NELAC's impact on laboratory data quality. Consider quantitative independent study? (6/6/03 Open Forum Issues 4 & 6)	
9	Ms. English will request additional information about the status of the national database from the National Database Committee chair and any other appropriate parties to enable ELAB to make a valid assessment of the issue.	

Attachment A

10	Ms. English will draft letter to recommend that EPA advise	
	NELAC to develop the degree of mutual reciprocity necessary to	
	reduce the number of primary accreditations required and to	
	develop a broader agree of acceptance between analyte lists.	
11	Ms. English will forward information on the scheduling of future	
	ELAB teleconferences to Ms. Autry.	
12	Ms. Autry will issue a Federal Register notice seeking new ELAB	
	membership and process nomination forms returned to her.	

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Attachment C

Environmental Laboratory Advisory Board

Meeting Agenda 8:30 am - 12:30 pm Friday, June 6, 2003 Hyatt Regency Islandia San Diego, California

8:30am - 8:40am	Introduction of Board; Review of Meeting Rules	Lara Autry, Designated Federal Official
8:40am - 8:50am	Welcome and Review of Agenda	Zonetta English, Chair
8:50am - 9:00am	Reading/Review of Minutes from May 28, 2003 Meeting	Zonetta English
9:00am - 9:45am	Review of Action Items	Board
9:45am - 10:30am	Review of Past ELAB Recommendations	Board
10:30am - 11:00am	BREAK	
11:00am - 11:45am	Open Forum Issues	Board
11:45am - 12:15pm	New Business	Board
12:159m - 12:25pm	Action Items	Zonetta English
12:25pm - 12:30pm	Close	Lara Autry